d20 30 b

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
FACSIMILE: 214-655-8130

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

98-SWR-WL-16/8

September 9, 1998

Sharon Morgan
Owner
The Place
1260 North 4th Street
Laramie, WY 82070

Dear Ms. Morgan:

The inspection of your tanning facility, The Place located at 1260 North 4th Street, Laramie, WY 82070, on August 21, 1998, by Investigator Robert G. Antonsen revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act). The investigator documented significant items of noncompliance with the Federal Performance Standard for Sunlamp Products as prescribed in Title 21, Code of Federal Regulations, Part 1040. 20 (21 CFR 1040.20) in conjunction with tanning beds in operation at your facility. The inspection indicated noncompliances for UWE Germany Bronzarium M-95, model 7121/13R tanning beds.

The inspection revealed that the tanning beds were misbranded within the meaning of Section 502(f) of the Act. There were no user instruction manuals or documentation of lamp compatibility available for these tanning beds to provide adequate directions for use in such manner as necessary to protect users against potentially harmful exposure to ultraviolet radiation [21 CFR 1040.20(e)(1)]. In addition, the timer intervals have a timing error greater than 10% of the maximum timer interval of the product [21 CFR 1040.20(c)(2)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies regarding sunlamp products at your firm. It is your responsibility to assure that electronic sunlamp products are maintained so that they continue to comply with the provisions of the Act.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure, injunction, and/or civil money penalties, without further notice.

You should notify this office in writing 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Deborah M. McGee, Radiation Specialist, U.S. Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982, telephone (214) 655-8100, ext. 138.

Sincerely,

for Edward R. Esparza
Regional Food and Drug Director
Southwest Region

DM:dm